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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,772	11/09/2001	Robert L. Stout	31645	7479

7590 07/27/2005

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,772	STOUT ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1, 3-4, 6--9, 12, 14-15, 17-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-4, 6--9, 12, 14-15, 17-20 and 22-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. The Art Unit Location to which your application has been assigned at the USPTO is changed to Art Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.
2. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 09 May 2005 after a Final action mailed 07 January 2005. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 13 July 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 09 May 2005 has been entered. Accordingly an RCE has been established and the action on RCE follows.
3. Applicants' responsive Amendment filed 09 May 2005 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
4. In view of applicants' amendment and arguments presented in response filed on 09 May 2005 responding to Final Office Action mailed 07 January 2005 Examiner hereby withdraws objections to claims, 3 and 12 and rejections under 35 U.S.C. §112, first and second paragraphs, 35 U.S. C. §1002(b) and 35 U.S. C. § 103(a).

CLAIMS STATUS

5. Claims 2, 5, 10-11, 13, 16 21 and 25-51 are cancelled.
6. Claims 1, 3-4, 7-9 and 12 are amended.
7. Claims 1, 3-4, 6-9, 12, and 14-20 and 22-24 are pending and are examined on Merits.

CLAIM OBJECTION

8. The following claims are objected to for the reasons given below:
 - Claims 19-20 and 22-23 are objected to because at Line one of each one of the cited Claims, after the phrase "12," the word --wherein-- should be inserted. Appropriate correction is required.

Claim Rejections Under 35 U.S.C. § 112

9. In view of applicants' amendment filed 09 May 2005, following are new rejections to claims 1,3, 6, 12, 14-15, 17-18 and 22-24 under 35 U.S.C. §112, second paragraph.

10. Claims 1, 3, 6, 12,14-15, 17-18 and 22-24 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In order to clearly communicate the claimed subject matter in Claim 1, Examiner suggests to re-write Claim 1 as follows:

"A method to determine the presence of an active Angiotensin Converting Enzyme-inhibiting (ACE-inhibiting) drug in a fluid sample, said drug in its active state modifies the activity level of an enzyme on a substrate, wherein said substrate is a synthetic pentapeptide substrate or n- (3(2-furyl) acryloyl)-L-phenoxyanaylglycylcycine (FAPGG), said method comprising the steps of:

- a. bringing a first fluid sample obtained from a patient, wherein said sample may, or may not contain said ACE-inhibiting drug, said first sample being a serum or urine sample comprising said enzyme;
- b. adding a quantity of said substrate to said first fluid sample;
- c. measuring the activity level of said enzyme on said substrate;
- d. comparing said measured activity level with a standard activity level established by testing serum or urine samples that have a known quantity of active ACE-inhibiting drug present in said samples, wherein said standard samples are obtained from a plurality of individuals other than said patient; and
- e. determining the presence of said active ACE-inhibiting drug by said measured activity level."

- Claim 6 depends from the rejected claim 5 and is, therefore, rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.
- Recitation "selected" in Claims 6, 14, 17 and 22 is similar to the word "preferably" and is indefinite because it is not clear how and who can determine with clarity and accuracy when

the "selection" is to be exercised and what are the metes and bounds of the term. Appropriate correction is required.

- In order to clearly communicate the claimed subject matter in Claim 1, Examiner suggests to re-write Claim 1 as follows:

"A method to determine the presence of active ACE-inhibiting drugs present in a fluid sample, said ACE-inhibiting drugs in their active state modifying the activity level of a target enzyme on a substrate, wherein said substrate is a synthetic pentapeptide substrate or n-(3(2-furyl) acryloyl)-L-phenoxyanaylglycylcycine (FAPGG), said method comprising the steps of:

- f. bringing a first fluid sample obtained from a patient, wherein said sample may, or may not contain said ACE-inhibiting drugs, said first sample being a serum or urine sample;
 - g. adding a quantity of said substrate to said first fluid sample;
 - h. determining the activity level of said target enzyme on said selected substrate in said fluid sample at a first time to obtain a base line activity level;
 - i. comparing said measured activity level with a standard activity level established by testing serum or urine samples that have a known quantity of active ACE-inhibiting drugs present in said samples, wherein said standard samples are obtained from a plurality of individuals other than said patient; and
 - j. determining the concentration of said active ACE-inhibiting drugs in said first fluid sample."
- Recitation "including" in Claims 14, 15, 17-18 and 23 should be replaced with the term "comprising" for clearer comprehension.
 - Recitation "provide" in claim 17 is indefinite, because said recitation does not clearly define the metes and bounds of the claimed subject matter. Examiner suggests to replace the recitation, "provide" with the word, "obtain".
 - In order to clearly communicate the claimed subject matter in Claim 20, Examiner suggests to re-write Claim 20 as follows:
"The method of Claim 12, wherein said base line activity level represents said target enzyme's activity when no ACE-inhibiting drugs are present."

- In order to clearly communicate the claimed subject matter in Claim 24, Examiner suggests to re-write Claim 20 as follows:

"The method of Claim 12, wherein said activity level is correlated with the optical density at 340 nm (O.D._{.340}), and is inverse of the delta O.D._{.340} number."

All other claims depend directly/indirectly from the rejected claims (e.g., Claim 1 or 12) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Conclusions

11. For reasons aforementioned, no Claims are allowed.

However, as Examiner telephonically communicated on 14 July 2005 with applicants' representative, Mr. Tracey S. Truitt, Claims 1, 3-4, 6-9, 12, and 14-20 and 22-24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Bruce Campell, can be reached on (571)-272-0974 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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July 25, 2005

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